DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22ET; Docket No. CDC-2022-0060]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Traveler-based SARS-CoV-2 Genomic Surveillance. The information collection will monitor for the importation of SARS-CoV-2 variants among arriving international air travelers at select U.S. airports.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0060 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the

OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Traveler-based SARS-CoV-2 Genomic Surveillance – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The traveler-based SARS-CoV-2 genomic surveillance project was developed as a surveillance platform for early detection of imported and emerging SARS-CoV-2 variants among international air travelers arriving into the United States. Despite layered mitigation measures, international travel facilitates spread of SARS-CoV-2, including novel variants of concern (VOCs). Although SARS-CoV-2 genomic sequencing has increased significantly during the pandemic, there is still a gap in early detection of emerging variants among arriving travelers.

To address this gap, in September 2021, the Travelers' Health Branch, in collaboration with private partners, implemented a voluntary SARS-CoV-2 genomic surveillance program with the goal of early detection of novel VOCs. Surveillance for new and emerging variant strains among travelers can provide researchers and public health officials critical time to collect information about the transmissibility, virulence, and effectiveness of existing vaccines, diagnostics, and therapeutics. The project is conducted with external partners and groups within DGMQ and across CDC, including the Office of Advanced Molecular Detection. The program began at New York's John F. Kennedy International Airport in September 2021 and later expanded to include Newark Liberty International, San Francisco International, and Hartsfield-Jackson Atlanta International airports. Information collection for this project

is currently approved under a Public Health Emergency PRA Waiver.

Project data is collected as follows: a volunteer sample of travelers, 18 years and older, from selected flights from South Asia, South America, Europe, and southern Africa, complete an informed consent form and fill-out a questionnaire on enrollment at the airport. The questionnaire includes demographic, travel, and clinical information. The voluntary surveillance project also includes laboratory data collection as follows: airport collection of nasal samples from arriving travelers and follow-up collection of individual at-home saliva samples 3-5 days later. Travelers participating in individual, at home sample collection also complete an electronic health information questionnaire prior to submission of their samples and have the opportunity to fill out an evaluation survey.

CDC requests OMB approval for an estimated 169,433 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Participant with sample collected in-airport	Participant information intake form (for pooled testing)	88,400	1	1	88,400
Participant with sample	Participant intake form	44,200	1	1.5	66,300

collected at home	(for individual at-home testing)				
Participant with sample collection at-home	Evaluation Survey Form	44,200	1	20/60	14,733
Total					169,433

Jeffrey M. Zirger,

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Centers for Disease Control and Prevention.

[FR Doc. 2022-09786 Filed: 5/5/2022 8:45 am; Publication Date: 5/6/2022]